DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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WARNING LETTER

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

Soo Bong Choi, M.D., Ph.D
CEO and Chairman
Sooil Development Co., Ltd
111-1 Heukseokl-dong
Dongjak-Ku
Seuol, 156-071, Republic of Korea (South)

Dear Dr. Soo Bong Choi:

During an inspection of your firm located in Seoul, South Korea on June 21 through 23, 2004, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures insulin infusion pumps. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be **adulterated** within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the **Current Good Manufacturing Practice** (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, [redacted] were not properly controlled and were subsequently used in production. This resulted in the manufacture of 126 infusion pumps wi[redacted] and the recall of 96 infusion pumps shipped to [redacted] If you have not already done so, we encourage you to inform the [redacted] who received the remaining 30 nonconforming infusion pumps of the problem(s) with the pumps.

2. Failure to investigate, and maintain complaint files on complaints involving the possible failure of a device to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(a) and (c). For example, there wasn't any documentation available for the results of investigations conducted on complaint numbers [redacted] and [redacted] These two complaints involved [redacted]. A previous investigation regarding [redacted] had been conducted and

determined that the errors were due to [redacted]. There was no documented investigation conducted to determine if complaints [redacted], which were received after corrections were made, were due to [redacted]. Additionally, the insulin pumps maintain [redacted]; however, there wasn't any documentation to suggest that t[redacted] these two insulin pumps were reviewed.

3. Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics, as required by 21 CFR 820.250(a). For example, when testing the accuracy of insulin delivery, your firm selected pumps to test at random. The test procedure states [redacted] in performing testing. When questioned about the validity of the sample size, your firm could not provide statistical rationale to support the use [redacted]

4. Failure to evaluate whether there was any adverse effect on product quality after learning that test/measurement equipment was found not to meet its accuracy and precision limits, as required 21 CFR 820.72(a) and (b). For example, CAPA record, [redacted], described the discovery of a piece of equipment found to be out of calibration in the production area. An investigation was not documented or performed to evaluate the effect of the equipment found to be out of calibration on the production process.

5. Failure to document the results of the design validation in the design history file, as required by 21 CFR 820.30(g). For example, the documentation of the bolus and basal infusion testing involving the dispensing software was incomplete. Additionally, as part of your software validation, the report titled '[redacted] did not identify the lot numbers of the motor and gear assembly used, or the other components used in the device, such as the MCU, PCB, and LCD.

6. Failure to maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example, the risk analysis conducted for the design change [redacted] used a different calculation of risk than that described in the [redacted]

7. Failure to adequately establish and maintain procedures for implementing corrective and preventive action (CAPA), which include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, as required by 21 CFR 820.100(a)(1). For example, your CAPA procedure, [redacted] dated February 18, 2002, requires [redacted]. However, [redacted] CAPAs were maintained in a log and there was not any assurance that CAPAs from sources [redacted] were being maintained.

8. Failure to document the CAPA activities including investigations of causes of nonconformities and dissemination of information about quality problems or nonconforming product to responsible parties, as required by 21 CFR 820.100 (a)(2). For example, the CAPA record [redacted] described the discovery of [redacted] The CAPA record did not provide a name or description of the equipment found to be out-of-calibration. An investigation was not documented or performed to determine why the equipment was allowed to go out of calibration.

9. Failure to document the approval, prior to issuance, of documents established to meet the requirements of 21 CFR Part 820, as required by 21 CFR 820.40(a). For example, the form titled [redacted] was not included with the master procedure, and the form was not listed as a valid form in the procedure.

10. Failure to maintain records of changes to documents, as required by 21 CFR 820.40(b). For example, the form titled [redacted] was found to have changed between April 30, 2004 and May 20, 2004. There wasn't any record documenting that a change was made by the firm. Additionally, the revision numbers on the forms were not changed to reflect a newly revised document.

11. Failure to document equipment maintenance activities, as required by 21 CFR 820.72(a). For example, the equipment records for the [redacted] did not include documentation of when the equipment was taken out of service.

12. Failure to document acceptance activities, as required by 21 CFR 820.80(e). For example, the identification of equipment used during testing was not recorded. [redacted] and should have been identified [redacted] in the event of an equipment calibration or maintenance problem.

13. Failure to have completed procedures for the acceptance or rejection of finished device production runs, as required by 21 CFR 820.80(d). For example, the [redacted]' test specification does not state that [redacted] This requirement is standard practice at the firm and is required by the relevant international standard.

14. Failure to maintain adequate procedures for acceptance activities such as inspections, tests, and verification activities, as required by 21 CFR 820.80(a). For example, the test record form, "[redacted]" includes [redacted]. The [redacted] specification is not listed in the test specification procedure.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Given the serious nature of these violations of the Act, the infusion pumps manufactured by your firm imported or offered for import are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they are adulterated. As a result, FDA may take steps to refuse these products, known as "detained without physical examination," until these violations are corrected.

If your devices are detained, in order to remove the devices from detention, you should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to re-inspect your facility to verify that the appropriate corrections have been made. In addition, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of government contracts.

We received your responses concerning our investigator's observations noted on the FDA 483. The first response dated July 9, 2004, was received July 16, 2004. A second response dated August 13, 2004, was received by our office on August 17, 2004. The third response, which was not dated, was received on September 1, 2004. A fourth response, which was not dated, was received on September 14, 2004. We will review the responses and communicate our comments to you. In the meantime, however, you should not delay your response to this warning letter.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, General Hospital Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Carolyn Niebauer, Chief, General Hospital Devices Branch.

If you need help in understanding the contents of this letter, please contact Carolyn Niebauer at the above address or at (240) 276-0343 or FAX (240) 276-0114.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Cc:
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